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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,209	11/28/2001	William D. Huse	P-IX 5066	3759

23601 7590 03/25/2003

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,209

Applicant(s)

HUSE, WILLIAM D.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 25-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-10, species of loxP cell sites in Paper No. 10 is acknowledged. The traversal is on the ground(s) that a thorough search of the claims of group I will likely reveal information relevant to the claims of group IV. Nevertheless, applicants admit that the claims of Group I and IV are patentably distinct. Upon reconsideration of the restriction requirement, the restriction between the two groups is revised. Group IV will be examined with Group I. Applicants' arguments with respect to the other Groups are not found persuasive. The information obtained for a cell will not anticipate or render obvious the different methods by which the cell is used. Each of the methods contains different process steps. The information for one process step is not co-extensive with the other processes.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election with traverse of the species of loxP cell sites and the modified peptide is acknowledged.

Applicants quote the relevant section in MPEP 806.04(f). As clearly stated by the cited section, the limitations recited in one species e.g., the structure of lox P will not be found to

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the other structurally different enzyme sites i.e., each nucleic acid will be different. Applicants' election of the species of the modified peptide in claim 2 is noted.

Claims 11-13 and 25-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Priority

The specification at page 1, line 3, claims priority to a provisional application. The application number of said provisional application has not been supplied.

Specification

The abstract of the disclosure is objected to because of the used of the phraseology often used in patent claims i.e., "comprising". Correction is required. See MPEP § 608.01(b).

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-10 do not sufficiently distinguish over a cell composition as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate a cell transfected with the variant nucleic acids with Cre/lox recombinase or a heterologous nucleic acid, as taught in the Examples. See MPEP 2105.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 24 are indefinite with the recitation of the variant nucleic acids "being expressed" in a different cell. Expressing relates to a process step, not to a characterization of the claimed cell. The rejection has similar import to claims 3, 4, 16 and 22-23.

B. Claims 2 and 15 are confusing in the recitation of "predetermined amino acid changes at preselected positions within a parent amino acid sequence". The base claims (1 and 14, respectively) do not recite for any amino acid, let alone, changes in any position of the amino acid. The term "predetermined", within the claimed context, is indefinite. It is not clear as to the standard or basis of said predetermination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e))

Claims 1, 3-10, 14 and 16-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouhassira et al (Blood, 1997).

Bouhassira et al discloses at page 3333, a non yeast eukaryotic cell i.e., MEL cells containing variant nucleic acids transfected to the cell by Cre recombinase at the two lox sites LoxP511 and LoxP, page 3335, Fig. 1; page 3336, col. 2 and page 3341. The specific cell composition of Bouhassira fully meets the broad claimed non-yeast eukaryotic cell comprising nucleic acid variants.

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Claims 1-10 and 14-24 are rejected under 35 U.S.C. 102(b) as being anticipated Biard-Piechczyk et al (Human Antibodies)

Biard discloses a cell composition comprising of variants of nucleic acid that expresses library of antibodies. See e.g., page 70 up to page 71. The specific cell composition of Biard fully meets the broad claimed non-yeast eukaryotic cell comprising nucleic acid variants.

Claims 1-4, 10, 14-16 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Le et al (Nucleic acids Research) or Thomas (Cell).

Le discloses a mammalian CHO cells comprising of a variant nucleic acids that has been predetermined from amino acid sequences. See e.g., page 4704, Materials and Methods section. The specific cell composition of Le fully meets the broad claimed non-yeast eukaryotic cell comprising nucleic acid variants.

Thomas discloses at page 419, col. 2, RESULTS section a mouse cell comprising of variants nucleic acids. The specific cell composition of Thomas fully meets the broad claimed non-yeast eukaryotic cell comprising nucleic acid variants.

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Claims 1-6, 8, 10, 14-17, 20 and 22-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Choi et al (Nucleic Acids Research).

Choi discloses a plant and fungal cell composition comprising a variant (library) of nucleic acids. See e.g., Fig. 1, page iii; page vii. Accordingly, the specific cell composition of Choi fully meets all the claimed limitation of the broad cell composition.

Claims 1, 10, 14 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Treco et al (6,063,630) or Stemmer (6,132,970).

Treco discloses a mammalian cell composition comprising of different nucleic acids composition. See e.g., col. 6, line 11 up to col. 8, line 20. The specific cell composition of Treco fully meets the broad claimed non-yeast eukaryotic cell comprising nucleic acid variants.

Stemmer discloses a cell composition comprising of variant nucleic acids at col. 49, line 24 up to col. 53, line 12. Accordingly, the specific cell composition of Stemmer fully meets the broad claimed non-yeast eukaryotic cell comprising nucleic acid variants.

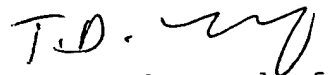
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
March 21, 2003